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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/978,633 · 11/25/97 RABBANI

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EXAMINER

SCHMIDT, M

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

11/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/978,633

Applicant(s)

Rabbani et al.

Examiner

Schmidt

Group Art Unit

1635

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/20/99.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 245-302 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 245-302 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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DETAILED ACTION

Double Patenting

1. Claim 245 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-24 of copending Application No. 08/978,632. Although the conflicting claims are not identical, they are not patentably distinct from each other for the same reasons of record as stated in the first Official action mailed 02/16/99.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. do not address the provisional rejection of claim 245.

Claim Rejections - 35 USC § 112

2. Claims 256-260 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the same reasons of record set forth in the Official action mailed 02/16/99.

Applicant's arguments filed 08/20/99 have been fully considered but they are not persuasive.

Applicant argues that the specification on page 56 explains the nature of the "specific complex" language used in claims 256-260 since the specification provides examples of ligand/receptor complexes being a "specific complex mediated by a ligand binding receptor". The

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examples taught in the specification do not clarify the metes and bounds of “specific complex” in terms of the “non-covalent binding” which comprises the specific complex. Neither the claims nor the specification clarify how the “non-covalent binding” comprises a “specific complex” such as “is mediated by a ligand binding receptor” (as in claim 257). The examples taught in the specification don’t teach how a ligand binding receptor “mediates” the “specific complex” as claimed such as in the Markush groups in claim 258 which include binding pairs not even containing a receptor as a part of the pair. For instance, it is not clear from the language of the claims whether the non-covalent binding is comprising the ligand/receptor interaction and thus whether the specific complex is the ligand/receptor interaction. If so, claim 258 is clearly indefinite for claiming “said ligand binding receptor” as selected from groups having interactions such as antigen/antibody interactions and other such interactions that do not comprise a receptor interaction. In summary, neither the specification, the claims nor applicant’s arguments have addressed the metes and bounds of the claimed “specific complex” in relation to the non-covalent binding it comprises and more specifically, in view of the unclear relationship “wherein said specific complex is mediated by a ligand binding receptor (claim 257).”

3. Claims 245-302 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the same reasons of record set forth in the Official action mailed 02/16/99.

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Applicant's arguments filed 08/20/99 have been fully considered but they are not persuasive.

Applicant argues that "specific examples need not be given in the specification in order to satisfy the statutory requirements for enablement. All that is required is that the disclosure be enabling... so that a person skilled in the art can practice the claimed invention, without undue experimentation. The fact that the same experiments for the U1 constructs were not specifically applied to the multicassette A, B, C and T7 polymerase constructs does not render that latter nonenabling." Applicant does not further address the enablement of the claimed constructs applied to whole organisms as broadly claimed.

Examiner acknowledges that the existence of working examples is only one factor to consider in determination of whether undue experimentation would be required to make and/or use the invention (see MPEP 2164.01 (a)). The instant enablement rejection centers on weighing the factors to be considered in determination of whether any necessary experimentation would be "undue" found in MPEP 2164.01 (a). Since the scope of the instant claims reads on a broad scope of possible nucleotide constructs, and the specification as filed only teaches to make and use specific antisense expression constructs, the instant enablement rejection aims to address the factors geared toward antisense expression in cells, including whole organisms. The unpredictability in the antisense art was discussed in the rejection to teach the lack of guidance in the art for design and expression of any antisense in a cell, especially a whole organism. The lack

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of general guidelines in the art for such administration of antisense for expression, leads to a lack of enablement for any such applications to whole organisms as broadly claimed.

4. Claims 245-262, 267-280 and 285-298 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the same reasons of record set forth in the Official action mailed 02/16/99.

Applicant's arguments filed 08/20/99 have been fully considered but they are not persuasive.

Applicant argues that working examples are not required for purposes of satisfying the written description statute. However, the interim guidelines for written description clearly describe criterion for meeting the written description such as providing a proportional amount of written description is necessary for the amount of unpredictability in the art. In the instant case, the specification as filed teaches only prophetically the majority of the constructs for the breadth claimed, and does not clearly describe to one skilled in the art that the inventor was in possession of the genus of claimed constructs considering the high level of unpredictability in the gene therapy and antisense art, the suggested applications for the prophetic constructs taught for producing a product in a cell, such as antisense.

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Claim Rejections - 35 USC § 102

5. Claims 245-302 are rejected under 35 U.S.C. 102(e) as being anticipated by Curiel et al (Patent 5,521,021), for the same reasons of record set forth in the Official action mailed 02/16/99.

Applicant's arguments filed 08/20/99 have been fully considered but they are not persuasive.

Applicant contends that there is a lack of material identity between Curiel's patent and the instant claimed invention. The broad scope of the instant claims reads on virtually any nucleic acid construct for expression of a product in a cell. It is clear that Curiel teaches constructs falling within the scope of the invention as broadly claimed. It is therefore not clear to examiner how the constructs taught by Curiel et al. would be considered to lack material identity for the breadth of possible constructs instantly claimed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *George Elliott, Ph.D.* may be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

M. M. Schmidt
November 8, 1999

A handwritten signature in cursive script, reading "George C. Elliott".

George C. Elliott, Ph.D.
Supervisory Patent Examiner
Technology Center 1600